SYNOPSYS®

Point of Care (POC) 3D Printing

Solutions with Simpleware Software

Anatomical 3D Printing for Better Patient Intervention Outcomes

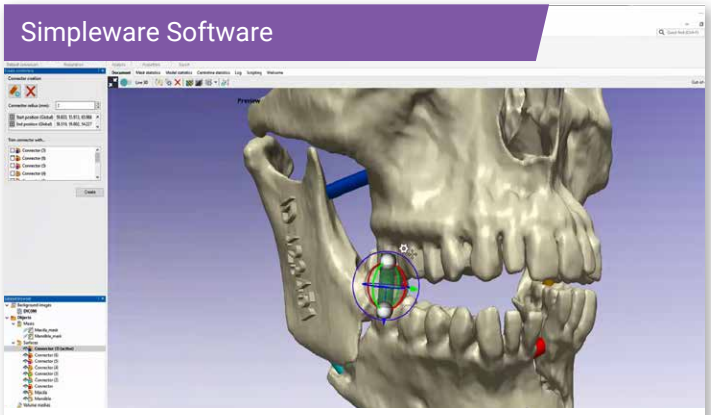
Simpleware for POC 3D Printing

Improve Patient-Specific Care

Point-of-Care (POC) 3D printing allows clinical professionals to create patient-specific anatomical models. Whether practicing a surgical procedure, testing medical device deployment or communicating with patients, 3D printed models bring many benefits for clinicians and patients.

- Optimize surgical planning with realistic, hands-on aids based on actual anatomies.
- Reduce the cost of testing different medical device options through 3D printed part-anatomy combinations.
- Use models to help visualize treatment options when speaking to patients.
- Enhance surgical training by using models when real anatomies are not available.
- Develop on-site software and hardware hubs to reduce turnaround time for scanning and printing.
- Easily combine models with complementary workflows such as VR and AR.

Simpleware Software



Intuitive & Powerful Software

The extensive image processing and 3D printing tools available in Simpleware software enable you to generate high-quality patient-specific anatomical models with minimal time and effort. Use 3D printed models for communication, training, and to inform diagnostic decisions.

- Easy-to-learn and use: Intuitive interface with quick-and-easy access to all tools and features.
- Accurate and reliable: High-quality anatomical models to practice and plan complex surgical procedures.
- Customizable: Automate repeatable tasks and operations with scripting and plug-ins.
- Print-ready: Direct link to compatible 3D printers.
- Fully supported: All licences come with full support from our expert team of application engineers.
- FDA, CE, and ISO compliant: Medical device software cleared for end-to-end diagnostic 3D printing.

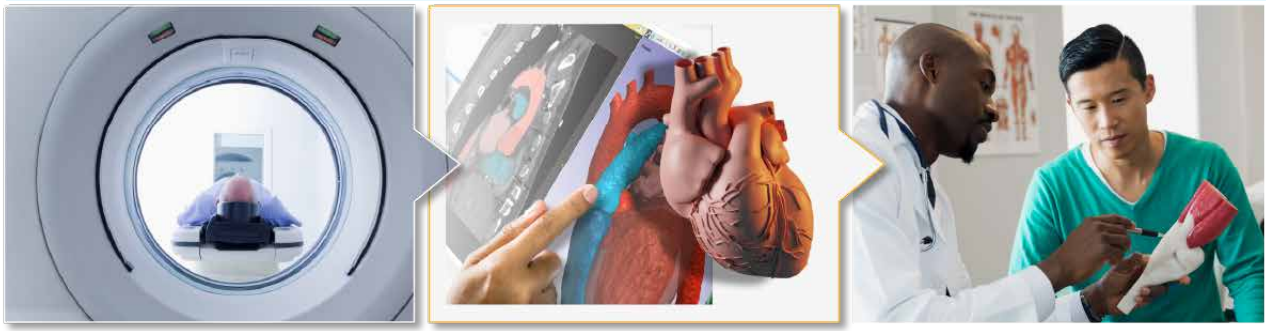
Complete Software & Printing Workflow with Regulatory Compliance

Simpleware Medical comes with FDA 510(k) clearance, CE marking and ISO 13485:2016 certification as a medical device. Use the software to import clinical MRI and CT scans over PACS and other systems for all your 3D image processing requirements.

FDA 510(k) Clearance for Diagnostic 3D Printing

Synopsys provides an integrated end-to-end POC solution for compatible printers, covering the entire workflow from DICOM data to printed models for planning surgeries, educating patients, and informing diagnostic decisions.

Integrated End-to-End POC Solution



MRI/CT Imaging

Image Processing & 3D Anatomical Printing

Surgical Planning/ Patient Education

Validated 3D Printers

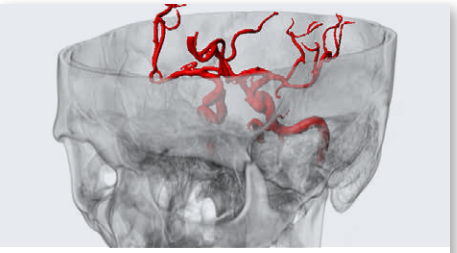
The following printers have been validated for use with Simpleware Medical as part of an end-to-end FDA-cleared workflow.

Print Vendor	Printer Model	Material	Anatomical Region
Formlabs	Form 3B Form 3BL Form 4B	Standard Grey Standard White Standard Clear	Orthopedics Maxillofacial Cardiac
HP	Jet Fusion 580	HP 3D HR CB PA 12	Orthopedics Maxillofacial Cardiac
Stratasys	J5 MediJet J5 Digital Anatomy	Elastico	Cardiac
Stratasys	J750 J750 DAP J850 DAP	Agilus30Clr	Cardiac
Stratasys	J750 J750 DAP J850 DAP J5 MediJet J5 Digital Anatomy	Vero PureWhite Vero Gray Vero Clear Vero Black Vero WhitePlus Vero Yellow Vero Cyan Vero Magenta MED610 MED615RGD	Orthopedics Maxillofacial Cardiac

Simpleware Medical works with printers designed for medical applications such as patient-specific anatomical models, surgical guides, and design and development of devices. Printers offer multiple options for materials and processes based on your needs and the number of models required. The resulting models are realistic, patient-matched, and able to capture complex anatomical features. Depending on the printer, you can also create 3D prints in materials that emulate the feel and appearance of body parts, making it easier to practice surgical procedures and communicate with patients.

From Image Processing to Model Generation

Image Processing | **Auto Segmentation**



Import, Registration & Visualization

Import Modalities

- MRI
- CT
- Micro-CT
- Ultrasound
- 2D X-ray images

Registration Options

- Co-registration of multiple 2D and/or 3D datasets
- Store and manage DICOM tags
- Anonymization
- Compatible with PACS

Object Visualization

- 3D live mode for instant updates
- Range of 2D and 3D visualization options
- Overlay surface contours in 2D
- Interactive image reslicing with multiplanar reconstruction mode

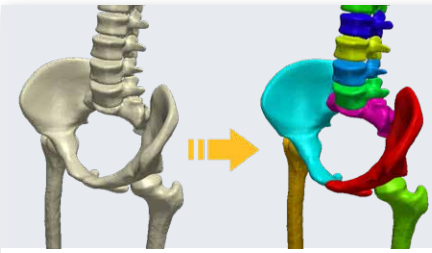


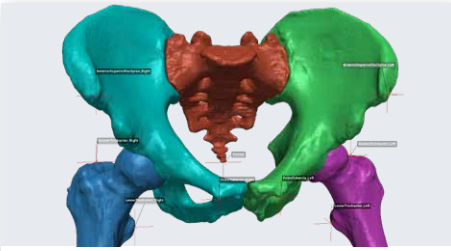
Image Processing

Image & Mask Filters

- Noise reduction
- Smoothing/morphological filters
- Align, rescale and resample
- Robust Boolean operations

Segmentation

- Threshold, floodfill and painting
- Interactive 3D editing tools
- Advanced region-growing tool
- Contour-based magnetic lasso
- Tools for handling poor contrast, artefacts and low quality data
- 3D wrap tool for scaffold-based segmentation
- Split tool to separate parts automatically
- Greyscale-based slide-to-slice propagation and interpolation
- Local surface correction to compensate for artefacts
- De-stepping



AI Segmentation & Landmarking*

- Ankle CT segmentation and landmarking
- CMF CT segmentation and landmarking
- Heart CT segmentation and landmarking
- Heart Valve analysis
- Hip CT segmentation and landmarking
- Hip Revision CT segmentation and landmarking
- Knee CT segmentation and landmarking
- Knee MRI segmentation and landmarking (including cartilage)
- Shoulder CT segmentation and landmarking
- Spine CT segmentation

All toools use fully automated AI-based machine learning

Have Confidence in your Models

Simpleware software is ideal for processing medical image data into 3D models for pre-surgical planning and 3D printing. Achieve reliable results every time with straightforward export of robust 3D printing files. Take advantage of dedicated tools to prepare complex surgeries and create patient-matched models for customized treatment plans.

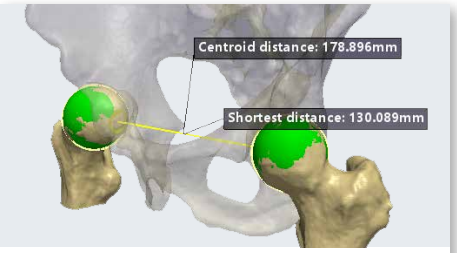
Customize your Workflow with Scripting

All functionality within Simpleware products is accessible from a fully documented API, with bindings available for Python, C# and Java. Use this API to automate repeatable workflows, build wizards and integrate custom plugins. By using our macro recording functionality, you can generate code without needing any prior experience, accelerating routine tasks and scaling up workflows.

*For non-clinical research use only - not cleared for use as a medical device

From Image Processing to Model Generation

Measurements | Surface Tools | 3D Printing



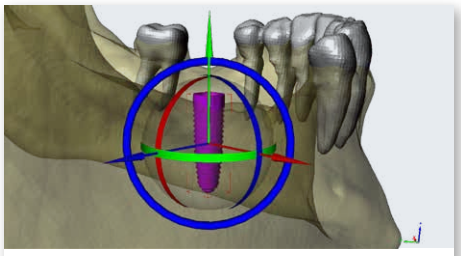
Measurements & Statistics

Interactive Tools

- Simple quick statistics and measurements
- Generate and probe centerlines networks
- 2D & 3D shape fitting and statistics
- Wall thickness analysis

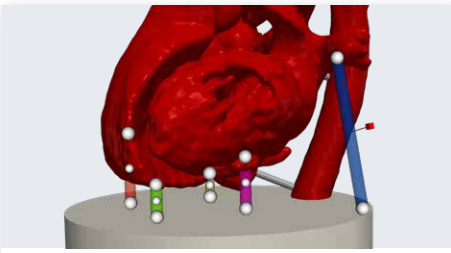
Statistics Framework

- Thoroughly interrogate image data, generated models, or centerlines
- Extensive range of metrics
- Highly flexible for creating custom statistics templates
- Generate PDF reports describing your data



Working with Image & CAD Data

- Import CAD files (STL, STEP, IGES)
- Automatic fixing of erroneous CAD data on import
- Automatic snap or landmark-based registration
- Surface deviation analysis for comparing objects
- Robust Boolean operations
- Surface filters to smooth, decimate, resurface, fill holes
- Surface editing tools to group/ungroup, extrude, hollow, clip
- Sweep pipes/tubes along centerlines
- Preserve CAD edges when combined with image data
- Import and interactively position SOLIDWORKS® parts or assemblies with 3D image data
- Automatically update design changes made in SOLIDWORKS



3D Printing Toolkit

- Dedicated tools to cut, hollow, emboss text, create connectors
- Create interlocking 3D parts using pins-and-sockets
- Check models before export

Cutting Guides Design Tool*

- Efficiently design patient-specific bone cutting guides
- Create cutting track, pin/drill holes and a base
- Revisit and modify designs, and regenerate the model
- Guides fit exactly on the region of the bone to be cut during surgery

Export Formats

- 3MF
- STL
- OBJ
- PLY
- 3D PDF
- VRML

Integrate Image and Design Data

Unique capabilities allow you to combine computer-aided design (CAD) models with 3D image data to capture realistic anatomical details whilst accurately maintaining the design features of the CAD data. Avoid the difficulties associated with combining multiple sources of data in different formats by working directly with powerful image and CAD tools within the Simpleware software environment.

Improve 3D Printing Workflows

Simpleware software is accessible to both beginners and more advanced users. The intuitive interface provides quick-and-easy access to a range of powerful tools tailored for 3D printing. The Simpleware 3D printing toolkit delivers accurate models, making it straightforward to save time and enhance the overall quality of the final product.

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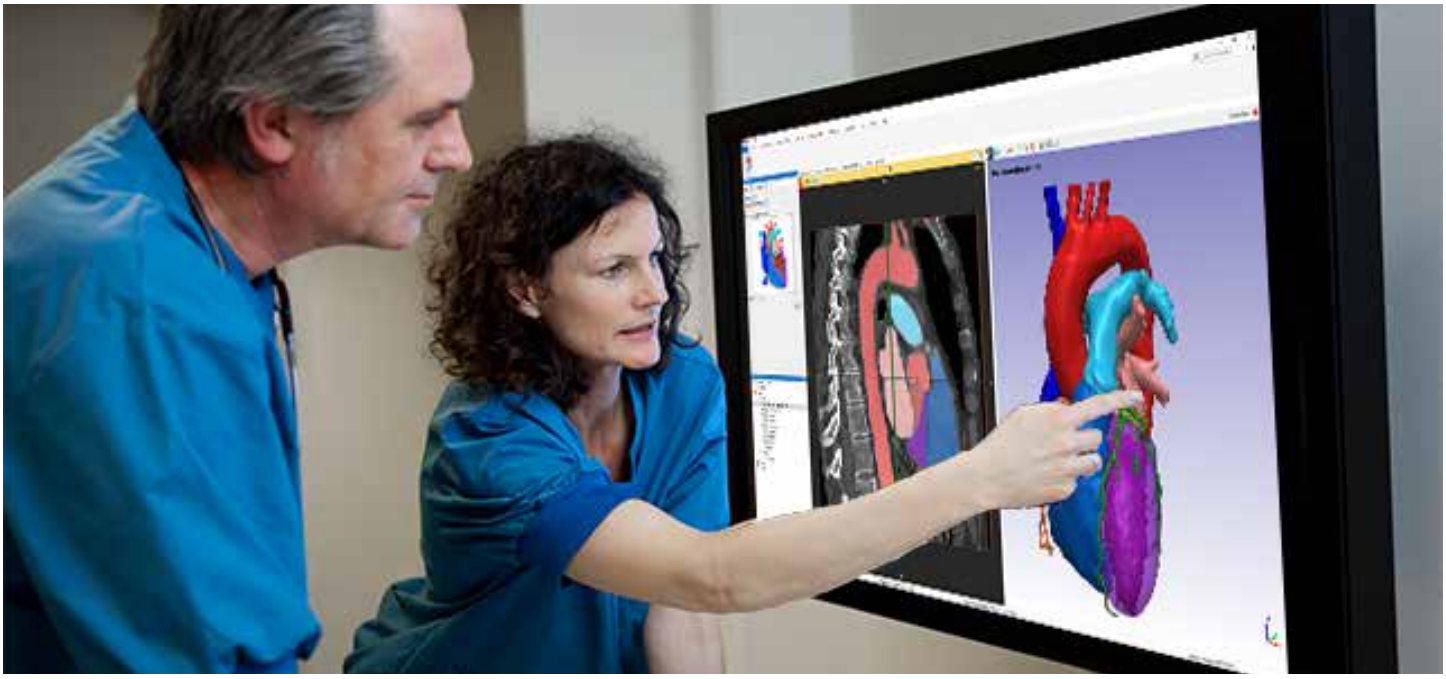

State-of-the-Art Technology

Our industry-leading 3D image processing platform leverages patented technology and enables comprehensive analysis of even the most complex anatomical scans. Increase confidence in clinical decision-making through reliable, repeatable software workflows.

Expert Support and Customization

All licenses come with full support from our team of experts. Our engineers can help you develop your unique and customized workflows, ensuring your use of the software is as efficient as possible, and your final output matches your requirements. Learn how to get the most out of the software with one-to-one sessions, web meetings and tailor-made training courses.

Ease-of-Use

Simpleware software is accessible to both beginners and more advanced users who need insights from medical image data. Streamline your software resources with a complete medical image processing platform for your R&D workstations, radiology departments, or other clinical environments.

Try Simpleware Software

Try the software for yourself with a free evaluation version, available on our website. The trial is fully functional and gives you access to the complete Simpleware software suite, a full range of tutorials and technical support.

FDA 510(k) CLEARED

CE 2797

bsi. ISO 13485:2016 Medical Device Quality Management

For more information, go to www.synopsys.com/simpleware

Email: simpleware@synopsys.com

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07/04/24.sw-brochure-3Dprint-poc-letter.